

**REMARKS**

Claims 1-28, 30, and 34-172 are pending. Claims 1, 25-28, 30, 34 and 35 have been amended to incorporate allowable subject matter in order to expedite prosecution, claims 29 and 31-33 have been cancelled without prejudice or disclaimer and new claims 36-172 have been added. Support for the new claims can be found in the specification including the original claims and the figures, for example, see original claims 1-35 and pages 8-9 of the specification. Reconsideration in view of the above amendments and following remarks is respectfully requested.

Applicants gratefully acknowledge the Office Action's indication that claims 29 and 33 define patentable subject matter. As claim 1 incorporates allowable subject matter of claim 29, claims 30, 34 and 35 incorporate allowable subject matter of claim 33 and since the remaining claims depend from the above claims, Applicants submit that claims 1-28, 30, 34 and 35 are in condition for allowance. Similarly, new claims 36-172, for the reasons set forth herein below, are patentable over the prior art of record.

I. 35 U.S.C. §102(b)

A. Sakai

The Office Action rejects claims 1, 2, 13-15, 18, 20-22, 25-28, 30-31, and 34-35 under 35 U.S.C. §102(b) over Sakai et al (hereinafter “Sakai”). Claim 31 has been cancelled without prejudice or disclaimer, therefore the rejection of claim 31 is moot. Because Sakai fails to disclose or suggest all the features of the remaining claims, the rejection is respectfully traversed.

Applicants respectfully submit that claim 1 recites the limitation of irradiating said biological material with a suitable ionizing radiation at an effective rate for a time effective to sterilize said biological material, wherein at least one sensitizer is added to said biological material prior to irradiating, as previously recited in allowable claim 29. Therefore, Applicants respectfully submit that claim 1 is allowable.

Applicants respectfully submit that claims 30, 34 and 35 recite the limitation of adding to a biological material at least one stabilizer in an amount effective to protect said biological material from said ionizing radiation, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof, DMSO, trehalose, mannitol, glutathione, tocopherol, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, polyhydric alcohols, rutin and other flavanoids, as previously recited in allowable claim 33.

Applicant notes that DMSO, trehalose, mannitol, and polyhydric alcohols were added to the Markush group. The cited art, however, fails to disclose or suggest a stabilizer including

DMSO, trehalose, mannitol, or polyhydric alcohols. As such, Applicants respectfully submit that claims 30, 34 and 35 are allowable.

For at least the reasons set forth above, it is respectfully submitted that claims 1, 30, 34 and 35 are allowable. Claims 2, 13-15, 18, 20-22 and 25-28 depend from claim 1 and are allowable for at least the same reasons, as well as their added features and the combinations thereof. Withdrawal of the rejection is respectfully required.

B. Chandekar

The Office Action rejects claims 1, 2, 4-8, 14, 19, 21, 22, 25-28, 30, 32, 34 and 35 under 35 U.S.C. §102(b) over Chandekar et al (hereinafter “Chandekar”). Claim 32 has been cancelled without prejudice or disclaimer, therefore the rejection of claim 32 is moot. Because Chandekar fails to disclose or suggest all the features of the remaining claims, the rejection is respectfully traversed.

Applicants respectfully submit that claim 1 recites the limitation of irradiating said biological material with a suitable ionizing radiation at an effective rate for a time effective to sterilize said biological material, wherein at least one sensitizer is added to said biological material prior to irradiating, as previously recited in allowable claim 29. Therefore, Applicants respectfully submit that claim 1 is allowable.

Applicants respectfully submit that claims 30, 34 and 35 recite the limitation of adding to a biological material at least one stabilizer in an amount effective to protect said biological material from said ionizing radiation, wherein said at least one stabilizer is selected from the

group consisting of: ascorbic acid or a salt or ester thereof, DMSO, trehalose, mannitol, glutathione, tocopherol, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, polyhydric alcohols, rutin and other flavanoids, as previously recited in allowable claim 33.

Applicant notes that DMSO, trehalose, mannitol, and polyhydric alcohols were added to the Markush group, however, the cited art fails to disclose or suggest a stabilizer including DMSO, trehalose, mannitol, or polyhydric alcohols. As such, Applicants respectfully submit that claims 30, 34 and 35 are allowable.

For at least the reasons set forth above, it is respectfully submitted that claims 1, 30, 34 and 35 are allowable. Claims 2, 4-8, 14, 19, 21, 22, and 25-28, depend from claim 1 and are allowable for at least the same reasons, as well as their added features and the combinations thereof. Withdrawal of the rejection is respectfully required.

C. Baquey

The Office Action rejects claims 1, 2, 4-6, 9, 14, 18, 20-23, and 25-28 under 35 U.S.C. §102(b) over Baquey et al (hereinafter “Baquey”). Because Baquey fails to disclose or suggest all the features of the claims, the rejection is respectfully traversed.

Applicants respectfully submit that claim 1 recites the limitation of irradiating said biological material with a suitable ionizing radiation at an effective rate for a time effective to sterilize said biological material, wherein at least one sensitizer is added to said biological material prior to irradiating, as previously recited in allowable claim 29. Therefore, Applicants respectfully submit that claim 1 is allowable.

For at least the reasons set forth above, it is respectfully submitted that claims 1 is allowable. Claims 2, 4-6, 9, 14, 18, 20-23, and 25-28, depend from claim 1 and are allowable for at least the same reasons, as well as their added features and the combinations thereof. Withdrawal of the rejection is respectfully required.

D. Field

The Office Action rejects claims 1, 2, 5, 10, 14, 19, 22 and 25-28 under 35 U.S.C. §102(b) over Field et al (hereinafter "Field"). Because Field fails to disclose or suggest all the features of the claims, the rejection is respectfully traversed.

Applicants respectfully submit that claim 1 recites the limitation of irradiating said biological material with a suitable ionizing radiation at an effective rate for a time effective to sterilize said biological material, wherein at least one sensitizer is added to said biological material prior to irradiating, as previously recited in allowable claim 29. Therefore, Applicants respectfully submit that claim 1 is allowable.

For at least the reasons set forth above, it is respectfully submitted that claims 1, 30, 34 and 35 are allowable. Claims 2, 5, 10, 14, 19, 22 and 25-28, depend from claim 1 and are allowable for at least the same reasons, as well as their added features and the combinations thereof. Withdrawal of the rejection is respectfully required.

**II. 35 U.S.C. §103(a)**

**A. Sakai**

The Office Action rejects claims 4, 6, 11, 12, 16, and 17 under 35 U.S.C. §103(a) over Sakai. Because Sakai fails to disclose or suggest all the features of the claims, the rejection is respectfully traversed.

Applicants respectfully submit that claims 4, 6, 11, 12, 16, and 17 depend from claim 1 and are allowable for at least the same reasons set forth above with respect to claim 1, as well as their added features and the combinations thereof. Withdrawal of the rejection is respectfully required.

**B. Sakai or Chandekar or Field in view of Horowitz**

The Office Action rejects claim 3 under 35 U.S.C. §103(a) over Sakai or Chandekar or Field in view of Horowitz et al (hereinafter Horowitz). Because the references, alone or in combination, fail to disclose or suggest all the features of the claim, the rejection is respectfully traversed.

Applicants respectfully submit that claim 3 depends from claim 1 and are allowable over Sakai or Chandekar or Field for at least the same reasons set forth above with respect to claim 1. Horowitz fails to cure these deficiencies. Therefore, Applicants respectfully submit that claim 3 is allowable for at least the same reasons set forth above with respect to claim 1, as well as its added features and the combination thereof. Withdrawal of the rejection is respectfully required.

C. Baquey

The Office Action rejects claim 24 under 35 U.S.C. §103(a) over Baquey. Because Baquey fails to disclose or suggest all the features of the claim, the rejection is respectfully traversed.

Applicants respectfully submit that claim 24 depends from claim 1 and is allowable for at least the same reasons set forth above with respect to claim 1, as well as their added features and the combination thereof. Withdrawal of the rejection is respectfully required.

**III. New Claims 36-172**

By this Amendment, claims 36-172 are added to the Application. Claims 36-172 recite features of the preferred embodiment(s). It is respectfully submitted that the new claims are allowable over the references of record for the reasons discussed above in connection with claims 1-28, 30, 34 and 35.

Specifically, claims 36-56 depend from claim 30 and are allowable for at least the same reasons as claim 30, as well as their added features and the combinations thereof. Claims 57-83 depend from claim 34 and are allowable for at least the same reasons as claim 34, as well as their added features and the combinations thereof. Claims 84-110 depend from claim 35 and are allowable for at least the same reasons as claim 35, as well as their added features and the combinations thereof.

Additionally, claim 111 includes allowable subject matter of original claim 29, and claims 112-141 depend from claim 111 and are allowable for at least the same reasons as claim 29, as well as their added features and the combinations thereof. Claim 142 includes allowable subject matter of original claim 29, and claims 143-172 depend from claim 142 and are allowable for at least the same reasons as claim 29, as well as their added features and the combinations thereof.




**CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance. If the Examiner believes that any additional changes would place the application in better condition for allowance, the Examiner is invited to contact the undersigned agent, Timothy M. Speer, at the telephone number listed below.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,  
FLESHNER & KIM, LLP



Donald McPhail  
Registration No. 35,811  
Timothy M. Speer  
Registration No. 47,355

P.O. Box 221200  
Chantilly, VA 20153-1200  
703 502-9440 DRM/TMS:mjc  
Date: March 21, 2003